IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, ex rel. SARAH BEHNKE,

Plaintiffs,

v.

CVS CAREMARK CORP., CVS CAREMARK Rx, LLC (f/k/a CAREMARK Rx, INC.), CAREMARKPCS HEALTH LLC, and SILVERSCRIPT INSURANCE COMPANY,

Defendants.

Civil Action No. 14-cv-00824 (MSG)

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS

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INTRODUCTION

This is a *qui tam* False Claims Act case in which the United States, after conducting an investigation, chose not to intervene. The Complaint filed by the *qui tam* relator, Sarah Behnke ("Relator"), consists primarily of conjecture, generalization, and "information and belief." It contains few allegations of *fact*, none of which, even if true, would support a conclusion that Defendants violated the False Claims Act ("FCA").

Relator's core contention is that Prescription Drug Event ("PDE") records prepared by CaremarkPCS Health, L.L.C. ("Caremark") with respect to certain generic drug prescriptions dispensed to Medicare Part D beneficiaries were "false" because they did not accurately report Caremark's "negotiated price" for those drugs. Relator was obliged to particularize her allegations under Federal Rule of Civil Procedure 9(b), which at a minimum required her to allege what specific "false" prices Caremark reported, what prices it *should* have reported as its "negotiated prices," and why. Relator's Complaint does none of this. It offers not a single example of a PDE record where the price submitted for a particular drug differed at all from the "negotiated price."

Instead, Relator speculates that such a discrepancy must have existed because Caremark's contracts with pharmacies—which she does not cite or describe in detail—allegedly contained *aggregate* reimbursement guarantees. Relator argues that these guarantees allowed Caremark to pay less to the pharmacies on an aggregate basis than it actually did for certain individual prescription fills. But Relator never explains how the aggregate guarantees functioned in general, much less how, specifically, Caremark's price reporting supposedly violated governing Medicare regulations.

This deficiency reveals Relator's claim to be not only too general to satisfy Rule 9(b), but also implausible under Rule 8(a). Under the governing Medicare regulation, the "negotiated

price" that Caremark was supposed to include on a PDE was the specific price applicable to each "particular drug" dispensed. That makes sense because PDE records are individual to each specific dispensing event and are prepared contemporaneously with the pharmacy claim. The regulation therefore contemplates reporting of individual prescription data, not "aggregate" guarantees that apply (if at all) across multiple prescriptions, and whose effects (if any) would not even be known at the time an individual prescription is filled and the PDE is prepared.

Furthermore, even if the regulations at issue were somehow ambiguous, Relator has pled no facts that would establish any *knowing* violations by Defendants. Relator identifies no guidance or authority that would support her position regarding the regulatory definition of "negotiated price," let alone guidance specific enough to support an inference that Defendants knowingly prepared PDEs that were inconsistent with the regulation.

Relator's Complaint suffers from numerous other flaws as well. Relator's "reverse FCA" claim is impermissibly duplicative of her other claims and fails to identify any payment obligation to the government, which is a *sine qua non* of such a claim. Relator names various Caremark entities as affiliates without alleging any particular conduct attributable to them (besides corporate affiliation), or based only on "information and belief." As to one Caremark affiliate, in fact, personal jurisdiction is lacking in Pennsylvania. And Relator alleges FCA violations stretching back to 2007, four years before she alleges Caremark even began submitting PDEs relating to Aetna.

Accordingly, Defendants respectfully ask this Court to dismiss Relator's Complaint in its entirety.

BACKGROUND

I. Caremark and Aetna

Defendant Caremark is a pharmacy benefit manager ("PBM"). Compl., Dkt. 1, ¶ 22. Aetna Life Insurance Company, which is not a party to this case, contracts with Medicare as a Part D Plan Sponsor and provides prescription drug plans that offer Part D benefits through various affiliates, including Aetna Health Management, LLC (collectively with Aetna, Inc. and/or its affiliates, "Aetna"). Compl. ¶¶ 33–34. At the time the action was filed, Relator was employed by Aetna as Senior Actuary/Head Actuary Medicare Part D. Compl. ¶ 9.

Caremark and Aetna executed a Pharmacy Benefit Management Subcontract Agreement dated July 27, 2010 ("2010 Agreement" or "2010 Agr."). Compl. ¶ 89. Pursuant to that agreement, which became effective on January 1, 2011, Caremark agreed to create, contract with, and administer a network of retail pharmacies at which Aetna beneficiaries could have their prescriptions filled. *Id.* Caremark also agreed to adjudicate and process for payment claims received from those pharmacies for prescriptions dispensed to Aetna beneficiaries. *Id.* ¹

II. Prescription Drug Reimbursement

Relator alleges that under the 2010 Agreement, Caremark was authorized to set and did set "MAC," or "Maximum Allowable Cost" prices for multi-source generic drugs. Compl. ¶ 94. Under the contract, Caremark "has the ability to change MAC prices," and Caremark frequently exercised this right. Compl. ¶ 95. MAC prices are set on a drug-specific basis, and thus could differ from drug to drug. *See* Compl. ¶¶ 100, 101, 114. The 2010 Agreement further required

¹ Relator also sues certain affiliates of Caremark: CVS Caremark Rx, L.L.C., CVS Caremark Corp., and SilverScript Insurance Company. As described *infra* Part V, Relator alleges no actionable facts pertaining to these entities. And this Court lacks personal jurisdiction over CVS Caremark Corp., which is now known as CVS Health Corporation. *See infra* Part IV.

that individual drug claims would be priced on a "pass through" basis, meaning that Caremark would charge Aetna the same price for the prescription that Caremark paid to the pharmacy.

Compl. ¶ 89.

Relator further alleges "on information and belief" that Caremark committed to aggregate financial guarantees in its contracts with pharmacies, and that it used these guarantees to earn a "spread" between the prices Caremark paid to pharmacies and the prices Aetna paid to Caremark. Compl. ¶¶ 156–157, 159. Relator alleges no factual details regarding any alleged aggregate guarantees contained in any contracts between Caremark and any pharmacy. The Complaint does describe the aggregate guarantee contained in Aetna's contract with Caremark, "referred to in the industry as a 'retail discount guarantee." Compl. ¶ 96. But Relator does not allege that Aetna's guarantee caused any claim to be false—her FCA claim evidently is based on the alleged guarantees between Caremark and the pharmacies.

III. PDE Records

Part D plan sponsors like Aetna, through their PBMs like Caremark, must submit certain data to the Centers for Medicare & Medicaid Services ("CMS") on a prescription-by-prescription basis. *See* Compl. ¶¶ 48, 71. This submission occurs via the PDE. *See* Compl. ¶ 48.

Each PDE corresponds to an individual drug claim, and is based on information as of the time the drug is dispensed. *See* Compl. ¶¶ 45–48. Relator alleges that after an individual submits a prescription to be filled at a retail pharmacy, the pharmacy "then submits required data elements to the Plan Sponsor or its [PBM]," and that this "typically takes place via real-time data transmissions between the pharmacy and the PBM." Compl. ¶ 46. If the claim for the prescription is not rejected, "the pharmacy receives payment authorization and co-pay information" and the "beneficiary pays the co-pay to the pharmacy and receives the prescription." Compl. ¶ 47. This claims data then feeds directly into the PDE: "Once the PBM

receives the data from the pharmacy, it submits the claims data to CMS, either directly or through the Plan Sponsor, via a Prescription Drug Event ('PDE') record that includes the drug price." Compl. ¶ 48. Accordingly, "each and every dispensing event" has a unique PDE, Compl. ¶ 71, which constitutes the "summary record that documents the final adjudication of a dispensing event by a PBM," Compl. ¶ 72.

The "drug price" that is submitted as part of the PDE is the Gross Covered Drug Cost, which breaks out the drug's ingredient cost, dispensing fee, and sales tax. *See*, *e.g.*, CMS, 2011 Regional Prescription Drug Event Data Technical Assistance Participant Guide, 5-1 to 5-2 (cited by Compl. ¶ 58). The Gross Covered Drug Cost that must be reported on the PDE is "th[e] actually paid cost[] incurred under a Part D plan, excluding administrative cost[], but including dispensing fee[]." 42 C.F.R. § 423.308 (cited by Compl. ¶ 59). This actually paid cost includes "[t]he share of actual cost . . . actually paid by the Part D plan that is received as reimbursement by the pharmacy." 42 C.F.R. § 423.308. The "actual cost" in turn is defined as "the negotiated price for a covered Part D drug when the drug is purchased at a network pharmacy." 42 C.F.R. § 423.100 (cited by Compl. ¶ 60). The negotiated price is the price that "[t]he Part D Sponsor (or other intermediary contracting organization) and the network dispensing pharmacy . . . have negotiated as the amount such network entity [pharmacy] will receive, in total, *for a particular drug.*" *Id.* (emphasis added) (cited by Compl. ¶ 61).

IV. Relator's Allegations

Relator charges violations of three provisions of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A), (B), and (G). *See* Compl. ¶¶ 168–75. All of her claims appear to be based on her theory that Caremark's PDEs were "false" because they reported inaccurate pricing for

individual drugs dispensed to Part D beneficiaries in light of Caremark's aggregate price guarantee agreements with pharmacies.²

PLEADING STANDARDS

To survive a motion to dismiss under Federal Rules of Civil Procedure 8(a) and 12(b)(6), "a complaint must do more than allege a plaintiff's entitlement to relief, *it must 'show' such an entitlement with its facts.*" *U.S. ex rel. Black v. Am. Soc'y for Eng'g Educ.*, Civ. No. 12-1139, 2014 WL 1765337, at *4 (E.D. Pa. May 2, 2014) (emphasis added) (quoting *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210–11 (3d Cir. 2009)). The "complaint must contain facts sufficient to nudge any claim 'across the line from conceivable to plausible." *U.S. ex rel. Forney v. Medtronic, Inc.*, Civ. No. 15-6264, 2017 WL 2653568, at *3 (E.D. Pa. June 19, 2017) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

"Because the False Claims Act . . . claims allege fraud, they are subject to the heightened pleading requirements of Federal Rule of Civil Procedure 9(b)." *U.S. ex rel. Schimelpfenig v. Dr. Reddy's Labs. Ltd.*, Civ. No. 11-4607, 2017 WL 1133956, at *2 (E.D. Pa. Mar. 27, 2017). Rule 9(b) requires plaintiffs "alleging fraud" to "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b).

² Relator has stipulated that she will not be pursuing claims under the Anti-Kickback Statute ("AKS"), as pled in paragraphs 166–167 of the Complaint and that she intends to seek dismissal of those claims without prejudice. Defendants accordingly are not responding substantively to those claims in this Motion and ask that those claims be dismissed in due course. To the extent any response to those claims is deemed required in the meantime, Defendants ask that they be dismissed for non-prosecution.

ARGUMENT

I. Counts I and II Should Be Dismissed Because Relator Does Not Adequately Allege Falsity.

To state a claim under sections (a)(1)(A) or (a)(1)(B) of the False Claims Act, 31 U.S.C. § 3729, a Relator must plead, among other elements, through factual allegations that are particular and plausible, that some claim, record, or statement was knowingly false. 3 U.S. ex rel. Petratos v. Genentech Inc., 855 F.3d 481, 487 (3d Cir. 2017). The sole theory of falsity on which Relator is proceeding is her contention that PDE records prepared by Caremark included pricing data that failed to reflect the "negotiated price" of drugs as that term is defined by regulation. That theory fails on two levels. First, Relator fails to plead with particularity the facts necessary to establish a scheme to submit false claims. Second, Relator fails to allege a plausible claim that Caremark violated Medicare regulations, let alone did so "knowingly."

A. Relator's Allegations Lack the Particularity Required by Rule 9(b).

To satisfy Rule 9(b)'s particularity requirement, a *qui tam* plaintiff may plead the details of particular false claims that were submitted to the Government for payment. Relator has not even attempted this; she pleads no details at all regarding any individual claims, much less why they are false.

Alternatively, "it is sufficient for a plaintiff to allege particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were

³ For Count I (subsection (A)), the Relator must show that Defendants presented or caused to be presented a claim for payment that was "false or fraudulent." *U.S. ex rel. Krahling v. Merck & Co.*, 44 F. Supp. 3d 581, 591 (E.D. Pa. 2014) (quoting *U.S. ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 305 (3d Cir. 2011)). The requirements for Count II (subsection (B)) are largely the same. The difference is Relator must show "the additional element of a false record or statement," but need not show that Defendants themselves were involved in presenting the materially related false or fraudulent claim. *Id.* at 592 (quoting *Wilkins*, 659 F.3d at 307).

actually submitted." *U.S. ex rel. Foglia v. Renal Ventures Mgmt.*, *LLC*, 754 F.3d 153, 156 (3d Cir. 2014) (internal quotation omitted). To plead an FCA claim by this method, "a complaint must provide 'all of the essential factual background that would accompany the first paragraph of any newspaper story—that is, the who, what, when, where and how of the events at issue." *U.S. ex rel. Whatley v. Eastwick Coll.*, 657 F. App'x 89, 93 (3d Cir. 2016) (unpublished) (quoting *In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 311 F.3d 198, 217 (3d Cir. 2002)). Relator's Complaint fails under this second alternative as well; her allegations fall woefully short of providing "particular details of a scheme to submit false claims."

The "scheme" Relator posits is that Caremark's PDE records reported its MAC point-of-sale pricing for individual prescriptions, when Caremark was required to report instead a different (lower) price that reflected the impact of negotiated aggregate price guarantees in Caremark's contracts with individual pharmacies. Even assuming arguendo that Caremark had been required to report its pricing on PDEs in the manner Relator claims (*but see discussion infra* Part I.B), Relator alleges no "particular details" of what the contracts between Caremark and the pharmacies required, or what the "negotiated prices" were, or what the impact was (if any) of the alleged contractual aggregate guarantees.

First, Relator alleges no particular facts as to what the "negotiated prices" actually were. Relator does not describe the terms on which Caremark agreed to reimburse pharmacies for each particular drug dispensed to Aetna Part D beneficiaries. Relator does not claim to have knowledge or allege facts regarding the actual contents of any of the relevant contracts. Relator identifies MAC prices that Caremark allegedly reported with respect to Aetna Part D beneficiaries, e.g., Compl. ¶ 101, but never once identifies a different "negotiated price" at which Caremark had agreed to reimburse any pharmacy for that same drug.

Second, Relator does not identify any of the other details of the relationships that would allow one to determine whether a "scheme" to report inaccurate prices existed.

- The Complaint does not name any specific pharmacy with which Caremark reached any particular terms.
- It does not identify when any of those unidentified terms with any of the unidentified pharmacies came into force, or for how long they remained in force.
- Relator identifies no individuals at Caremark or at any pharmacy who were involved in establishing or implementing such terms.

Third, the Complaint does not allege any details about the PDEs that allegedly were false or how they came to be submitted. Relator does not identify anyone at Caremark who was involved in generating PDEs, nor provide any details regarding how specifically Caremark generated false PDEs.

Fourth, Relator fails to specify how any alleged aggregate pricing guarantees could render false a PDE, which by definition reports an *individual* drug price as of the time of sale. The Complaint does not explain what price the PDE was supposed to report, if not the point-of-sale price, or how such a hypothetical price might be calculated. After all, an aggregate pricing guarantee by definition would apply to overall purchases of a certain drug or drugs depending on the totality of eligible purchases over a period of time, and would not likely apply to individual purchases at the point of sale. In any event, the Complaint provides no reason to believe Caremark's guarantee agreements with pharmacies operated any differently.

"Rather than containing details of the alleged scheme, the . . . complaint presents only the broad outlines, and the inferences it offers are not reasonably drawn." *Zwirn v. ADT Security Servs., Inc.*, 2014 WL 2932846, at *7 (D.N.J. June 30, 2014) (dismissing FCA claims for failure

to plead alleged scheme with particularity). The allegations must suggest more than a "mere opportunity for fraud," *Foglia*, 754 F.3d at 158; assertions that "amount to nothing more than speculation" necessitate dismissal. *Whatley*, 657 F. App'x at 95.

Courts in this Circuit and elsewhere have not hesitated to dismiss FCA lawsuits where, as here, a relator purports to allege a "scheme to submit false claims," yet fails to provide the "particular details" necessary to establish the essential factual background. *Foglia*, 754 F.3d at 156 (internal quotation omitted); *see*, *e.g.*, *U.S. ex rel. Whatley v. Eastwick Coll.*, Civ. No. 2:13-1226, 2015 WL 4487747 (D.N.J. June 23, 2015), *aff'd*, 657 F. App'x 89 (3d Cir. 2016); *Zwirn*, 2014 WL 2932846, at *6–8; *U.S. ex rel. Knisely v. Cintas Corp.*, 298 F.R.D. 229, 240 (E.D. Pa. 2014). The same result is appropriate here.

B. Relator's Allegations Do Not Support a Plausible Inference of Falsity.

Even had Relator alleged with particularity facts supporting the theory she espouses, her Complaint would not state a claim. Relator's allegations that there was a difference between the point-of-sale price, which Caremark reported on its PDEs, and the "negotiated" price are implausible in light of the relevant Medicare regulations.

Relator contends that Caremark was required to comply "with the Federal Regulations definition of Pass Through (42 C.F.R. § 423.308)." Compl. 110. But there is no regulatory definition of "Pass Through." The only relevant definition in the regulation Relator cites, 42 C.F.R. § 423.308, refers to the "actual costs (as defined by § 423.100 of this part) actually paid," 42 C.F.R. § 423.308 (emphases added). Actual cost, in turn, "means the negotiated price," which is the price a pharmacy agrees to receive "for a particular drug." 42 C.F.R. § 423.100 (emphases added). The mechanism for reporting the "negotiated price" to CMS is the PDE, see Compl. ¶¶ 46–48, 71, and CMS guidance expressly states "the PDE should reflect actual point-of-sale incurred costs." CMS, Announcement of CY 2014 Medicare Advantage Capitation

Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, 55 (Apr. 1, 2013)⁴ (emphasis added).

An aggregate guarantee is simply not the same thing as the actual point-of-sale incurred cost for an individual prescription of a particular drug. Relator offers no plausible allegation to the contrary. Thus, even taking as true her non-particularized allegation that Caremark made aggregate guarantees to pharmacies that differed from its aggregate guarantee to Aetna, one cannot reasonably infer that Caremark's PDEs were inaccurate.

C. Relator's Allegations Do Not Support a Plausible Inference of *Knowing* Falsity.

Even had Relator particularly or plausibly pled falsity—which she has not—the Complaint would be subject to dismissal because Relator fails to plead facts sufficient to infer that Defendants acted with requisite *knowledge* of any falsity. The False Claims Act does not impose liability for mere mistakes. Relator must show that Defendants acted "knowingly," 31 U.S.C. § 3729(a)(1)(A), (B), (G), meaning that Defendants had "actual knowledge" or acted "in deliberate ignorance" or "reckless disregard of the truth or falsity of the information," 31 U.S.C. § 3729(b)(1)(A). "Although Rule 9(b) permits a plaintiff to generally allege a defendant's mental state, the Third Circuit has read the Rule to still require plaintiffs 'to allege facts that show the court their basis for inferring that the defendants acted with scienter." *U.S. ex rel. Pilecki-Simko v. Chubb Inst.*, Civ. No. 06-3562, 2010 WL 1076228, at *7 (D.N.J. Mar. 22, 2010) (quoting *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1418 (3d Cir. 1997)).

To show a culpable mental state under the FCA, the legal obligation the defendant allegedly violated must be *clear* and not fairly debatable. *See U.S. ex rel. Quinn v. Omnicare*

⁴ Available at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2014.pdf.

Inc., 382 F.3d 432, 445 (3d Cir. 2004) ("[I]n light of the absence of a *clear obligation* to credit Medicaid and the absence of any Medicaid or other regulation requiring provider pharmacies to credit at a specific rate, we can not impose FCA liability on [defendant]." (emphasis added)). Courts overwhelmingly reject FCA claims where defendants acted in accordance with a reasonable—even if incorrect—interpretation of an ambiguous contractual or legal provision. See, e.g., U.S. ex rel. Purcell v. MWI Corp., 807 F.3d 281, 287–89 (D.C. Cir. 2015); U.S. Dep't of Transp. ex rel. Arnold v. CMC Eng'g, 567 F. App'x 166, 171 (3d Cir. 2014) (unpublished); U.S. ex rel. Thomas v. Siemens AG, 593 F. App'x 139, 144 (3d Cir. 2014) (unpublished); U.S. ex rel. Streck v. Allergan, Inc., 894 F. Supp. 2d 584, 593, 595 (E.D. Pa. 2012).

As explained above, Caremark's alleged interpretation of "negotiated price" was not only reasonable, it also was correct. *See supra* Part I.B. At a minimum, however, Relator fails to "plead sufficient facts that . . . Defendants' interpretation of the statutory and regulatory scheme was unreasonable," and has identified "nothing that 'warned [Defendants] away from the view [they] took." *Streck*, 894 F. Supp. 2d at 595–96 (last alteration in original) (quoting *Safeco Ins. v. Burr*, 551 U.S. 47, 70 (2007)). Relator's failure to plead a violation of a clear legal duty necessitates dismissal of her claims. *See id.*; *see also U.S. ex rel. Pilecki-Simko v. Chubb Inst.*, 443 F. App'x 754, 760–61 (3d Cir. 2011) (unpublished).

II. Count III Should Be Dismissed Because Relator Fails To Allege Any Obligation To Pay or Transmit Money to the Government.

Count III of the Complaint alleges that Defendants violated the "reverse false claims" provision of the False Claims Act, 31 U.S.C. § 3729(a)(1)(G). Compl. ¶ 175. To allege a plausible reverse false claims violation, Relator must adequately plead that Defendants (1) "knowingly" (2) "conceal[ed]" or "improperly avoid[ed] or decrease[d]" (3) "an obligation"

(4) "to pay or transmit money or property to the Government." 31 U.S.C. § 3729(1)(G). Relator does not adequately plead any of these elements.

To the extent Relator premises this claim on the same grounds as Counts I and II, it should be dismissed for the same reasons stated above. Count III should also be dismissed for the additional reason that "[c]laims raised under the FCA's reverse false claims provision 'may not be redundant of FCA claims asserted under other provisions of [the FCA]." *U.S. ex rel. Petratos v. Genentech, Inc.*, 141 F. Supp. 3d 311, 322 (D.N.J. 2015) (quoting *U.S. ex rel. Sobek v. Educ. Mgmt., LLC*, Civ. No. 10-131, 2013 WL 2404082, at *29 (W.D. Pa. May 31, 2013)), *aff'd*, 855 F.3d 481 (3d Cir. 2017). Count III is entirely redundant because it relies on all the same allegations as Counts I and II, explicitly incorporates Counts I and II in their entirety, and does not purport to add any further factual allegations. *See* Compl. ¶¶ 174–175.

Count III also warrants dismissal because Relator fails to allege any predicate "obligation." To plead a violation of the reverse false claims provision, there must be an obligation "existing at the time of the improper conduct to pay the Government funds." *U.S. ex rel. Petras v. Simparel, Inc.*, 857 F.3d 497, 506 (3d Cir. 2017). The FCA "defines 'obligation' as 'an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment." *Id.* at 504–05 (quoting 31 U.S.C. § 3729(b)(3)). The Complaint fails to identify any such "obligation," and it should be dismissed for this reason as well.

III. All Claims for Alleged Violations Prior to 2011 Should Be Dismissed.

Relator alleges that Defendants have caused the submission of false PDEs "since at least 2007." Compl. ¶¶ 2. Yet Relator claims that the 2010 Agreement pursuant to which Caremark provided PBM services to Aetna did not become effective until January 1, 2011. Compl. ¶ 89.

Relator makes no allegations that would support an inference that Caremark engaged in any conduct that could have affected PDEs submitted by Aetna to CMS prior to January 1, 2011. The Court should therefore dismiss all claims relating to PDEs submitted on behalf of Aetna beneficiaries prior to January 1, 2011. *See U.S. ex rel. Lord v. NAPA Mgmt. Servs. Corp.*, Civ. No. 3:13-2940, 2017 WL 5450757, at *9 (M.D. Pa. Nov. 14, 2017) (dismissing claims prior to and after a two-year period because plaintiff failed to plead specific facts that would lead to a "strong inference" that false claims were submitted outside that two-year period).

Furthermore, Relator alleges that the regulatory change which allegedly obligated Plan Sponsors to report to CMS drug prices on a "pass through" basis did not become effective until January 1, 2010. Compl. ¶¶ 61–62 (acknowledging that prior to 2010, CMS "allowed PDPs or PBMs to include in their reported prices the differences between what a PBM paid a pharmacy for a particular drug and the higher amount paid by a Plan Sponsor to the PBM under 'lock-in price' contracts"). At a bare minimum, all of Relator's claims for the period prior to January 1, 2010 should be dismissed.

IV. The Court Lacks Personal Jurisdiction over CVS Health Corporation (f/k/a CVS Caremark Corporation).

Relator's Complaint names as a defendant CVS Caremark Corporation, which is now CVS Health Corporation ("CVS Health"). *See* Declaration of Thomas S. Moffatt in Support of Defendants' Motion to Dismiss ¶ 1 ("Moffatt Decl."). This Court lacks personal jurisdiction over CVS Health because it has no connection to Pennsylvania.

"Federal courts ordinarily follow state law in determining the bounds of their jurisdiction over persons." *Daimler AG v. Bauman*, 571 U.S. 117, 125 (2014). Here, however, the relevant inquiry depends entirely on the Due Process Clause because Pennsylvania law authorizes personal jurisdiction to "the fullest extent allowed under the Constitution of the United States."

42 Pa. Cons. Stat. Ann. § 5322(b). In accordance with these constitutional limits, it is Relator's burden to prove sufficient "general or claim-specific contacts" between CVS Health and Pennsylvania. *Campbell v. Fast Retailing USA, Inc.*, Civ. No. 14-6752, 2015 WL 9302847, at *2 (E.D. Pa. Dec. 22, 2015) (Goldberg, J.) (quoting *Remick v. Manfredy*, 238 F.3d 248, 255 (3d Cir. 2001)). Relator has not, and cannot, meet her burden to "establish[] with reasonable particularity sufficient contacts." *Id.* (quoting *Provident Nat'l Bank v. Cal. Fed. Sav. & Loan Ass'n*, 819 F.2d 434 (3d Cir. 1987)).

A. CVS Health Is Not Subject to General Jurisdiction in Pennsylvania.

This Court lacks general jurisdiction over CVS Health because its "affiliations" with Pennsylvania are *not* "so continuous and systematic as to render [CVS Health] essentially at home in [Pennsylvania]." *Daimler*, 571 U.S. at 127 (quoting *Goodyear Dunlop Tires Operations, S.A. v. Brown*, 564 U.S. 915, 919 (2011)). CVS Health is organized under the laws of Delaware and has its principal place of business in Rhode Island. *See* Compl. ¶ 10; Moffatt Decl. ¶ 5. CVS Health is merely a holding company that issues stock and files reports with the Securities and Exchange Commission; it has no operations unrelated to its functions as a holding company. Moffatt Decl. ¶ 4. CVS Health has no assets, income, employees, facilities, or offices in Pennsylvania, and none of its limited business functions occur there. Moffatt Decl. ¶ 5. CVS Health is not authorized to do business in Pennsylvania, does not have a registered agent for service of process there, and is not regulated by any Pennsylvania state agency. *Id*.

Considering these facts about CVS Health in relation to their states, district courts in California and South Carolina held that they lacked general jurisdiction over CVS Health. *See Corcoran v. CVS Health Corp.*, 169 F. Supp. 3d 970, 981 (N.D. Cal. 2016) ("Even taking all of Plaintiffs' jurisdictional allegations as true, CVS Health's contacts do not rise to the level that it is 'essentially at home in the forum State.'" (quoting *Daimler*, 571 U.S. at 139)); *Callum v. CVS*

Health Corp., 137 F. Supp. 3d 817, 837 (D.S.C. 2015) ("[Thomas] Moffatt's affidavit establishes CVS Health is a holding company incorporated in Delaware with its principal place of business in Rhode Island. Plaintiff has not offered sufficient evidence showing CVS Health has an enduring relationship with South Carolina, as indicated by contacts that are substantial, continuous and systematic, so as to render it essentially at home in this forum."). The same conclusion applies here as to Pennsylvania.

B. CVS Health Is Not Subject to Specific Jurisdiction in Pennsylvania.

This Court lacks specific jurisdiction over CVS Health because this case does not "aris[e] out of or relate[] to [CVS Health's] contacts with [Pennsylvania]." *Campbell*, 2015 WL 9302847, at *4 (quoting *Helicopteros Nacionales de Columbia, S.A. v. Hall*, 466 U.S. 408, 414 n.8 (1984)). Relator offers no allegation that CVS Health "purposefully availed itself of conducting business in Pennsylvania" or that any "supposed contacts with Pennsylvania caused the [alleged FCA] violations to occur." *Id.* at *5. Nor could she. CVS Health has no operations unrelated to its limited functions as a holding company (e.g., issuing stock and filing SEC reports). Moffatt Decl. ¶ 4. As such, CVS Health—a separate and distinct corporation from Caremark—could not play any role in Pennsylvania relating to the allegations at issue in Relator's Complaint. *See* Moffatt Decl. ¶¶ 5–7.

V. All Claims Against Caremark Rx, L.L.C., CVS Health, and SilverScript Should Be Dismissed Because Relator Fails To Plead Their Conduct with Particularity.

Relator's Complaint names four corporate defendants, but only one of them,

CaremarkPCS Health, L.L.C. ("Caremark"), provided Aetna the PBM services that form the

basis of Relator's Complaint. Compl. ¶¶ 20, 22, 23. "[U]nder Rule 9(b), when there are multiple

defendants 'the complaint must plead with particularity by specifying the allegations of fraud

applying to each defendant." *Lord*, 2017 WL 5450757, at *7 (quoting *MDNet*, *Inc.* v.

Pharmacia Corp., 147 F. App'x 239, 245 (3d Cir. 2005)). Even if Relator had sufficiently alleged FCA claims against Caremark (she has not for all the reasons above), she has failed to do so as to Caremark Rx, L.L.C. ("Caremark Rx"), CVS Health, and SilverScript Insurance Company ("SilverScript"). Her claims against these three entities should therefore be dismissed.

The only basis Relator offers for naming Caremark Rx and CVS Health is that they are direct or indirect parent corporations of Caremark. See Compl. ¶ 11, 14, 20, 22–23. That is insufficient. Claims against a corporate parent should be dismissed unless the relator either pleads with particularity facts establishing that the parent corporation itself directly violated the False Claims Act, or pleads facts sufficient to pierce the corporate veil. See, e.g., U.S. ex rel. Polansky v. Exec. Health Res., Inc., 196 F. Supp. 3d 477, 512–17 (E.D. Pa. 2016) (dismissing FCA claims against parent corporations because relator failed to adequately plead direct involvement or veil piercing); Pilecki-Simko, 2010 WL 1076228, at *11–15 (same). Relator pleads no specific facts that would establish that either Caremark Rx or CVS Health directly participated in or had knowledge of any PDE records generated on behalf of Aetna Part D beneficiaries. Nor does Relator's Complaint contend that the corporate veil should be pierced, let alone plead any facts that would satisfy the Third Circuit's eight-factor test for veil piercing. See Polansky, 196 F. Supp. 3d at 515.

Regarding SilverScript, the Complaint offers no particular or plausible allegation that SilverScript had any knowledge of any alleged falsity in Caremark's PDEs. The only allegation of knowledge on SilverScript's part comes at the end of the Complaint in conclusory paragraphs parroting the statutory language. *See* Compl. ¶¶ 169, 171, 175. That defect warrants dismissal. *See, e.g., Pilecki-Simko*, 443 F. App'x at 760-61 (affirming dismissal because "conclusory allegations . . . do not allow [the Court] to draw the reasonable inference that [the defendant] was

liable for the misconduct alleged, which required knowledge that the claims were false");

accord, e.g., Twombly, 550 U.S. at 555. In addition, every critical assertion of fact Relator offers

to support the conclusion that SilverScript submitted false PDEs is made on "information and

belief." Compl. ¶ 130–134. Yet, in violation of the requirements governing "information and

belief" pleading, Relator fails to specify any particular or plausible basis for her information and

belief. See, e.g., Whatley, 657 F. App'x at 93; Rockefeller, 311 F.3d at 216–17.

CONCLUSION

For all these reasons, Defendants respectfully request that this Court grant the motion and

dismiss Relator's Complaint.

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